REMARKS

This is in response to the Office Action dated September 13, 2007.

Claim 16 was amended to correct a minor typographical error. No new matter has been added. Independent claim 1 and its dependent claims 2-46 and 49-58 and independent claims 47 and 59 are presented for consideration.

Claim Rejections - 35 U.S.C. §102

The Examiner has rejected claims 1, 4, 15, 17, 20, 24-26, 29, 35-37, 49-52, and 58 under U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,197,051 (Zhong). Applicants respectfully traverse.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. In order to anticipate, the elements of a reference must be present and arranged as required by the claim. See MPEP § 2131.

The present invention as set forth in independent claim 1 is directed to a stent having a coating comprising: (a) a primer layer having a polymer composition of two or more polymers, and (b) a single outermost drug reservoir layer having (i) a polymer composition of two or more polymers comprising a drug stabilizing polymer and (ii) one or more active agents; the primer layer polymer composition being distinct from the drug reservoir layer polymer composition.

The outermost drug reservoir layer protects and stabilizes the one or more active agents during sterilization and storage. The single outermost drug reservoir layer allows sufficient adhesion and flexibility to remain intact upon stent expansion and during a sustained period thereafter, release of efficacious amounts of the active agent at the site of stent expansion.

The present claims are not anticipated, nor rendered obvious by Zhong because the device of Zhong is both structurally and functionally different from the stent of the present system. First, Zhong does not teach or disclose each and every element of the claims. As detailed below, Zhong does not teach a single outermost drug reservoir layer comprising two or more polymers. Also, Zhong does not teach a composition that releases efficacious amounts of the active agent at the site of stent expansion over a sustained period of time. Instead, Zhong teaches bio-active agents that are covalently bound to the primer layer, and there is no teaching that the bound agents would be released in efficacious amounts over a sustained period as with the claimed invention.

Zhong discloses devices having bio-compatible substrate coatings. The bio-compatible coating of Zhong is formed from a composition comprising an aqueous emulsion or dispersion of a polycarbonate-polyurethane polymer having one or more emulsifying agents which include at least one organic acid functional group (e.g., see field of invention, summary of invention, detailed description and claims), and optionally polyfunctional cross-linking agents that are reactive with organic acid functional group (column 5, lines 28-40). This coating can also serve as a primer for a second coating layer which contains certain bio-active agents. (e.g., field of invention, column 3, lines 20-21, column 4, lines 39-41).

Nowhere in Zhong is it disclosed or suggested that these second layers contain two or more polymers. Zhong indicates that the bio-active agents for use in the bio-compatible coatings include those known in the art and indicates that any bio-active agent may be used in the second coating provided that it contains at least one organic acid functional group in its structure which can react with the polyfunctional cross-linking agent and still retain its bio-active function (column 7, lines 7-12). The teaching of Zhong is consistent throughout that the only requirement for the second

coating is that the bio-active agents contain at least one organic acid functional group. See also Example 2, the bio-active coating composition (1.2% aqueous solution of Heparin, 400 ml) was prepared by adding heparin powder to water (column 11, lines 38-46).

Zhong does not teach, disclose, or suggest a single outermost drug reservoir layer comprising two or more polymers, and is therefore structurally different from the present claims.

As set forth in the claims and the description of the present application, e.g., paragraph 16, the inventive coatings use a system with two or more polymers (e.g., a hydrophilic and a hydrophobic polymer), which allows outstanding adhesion to substrates and the flexibility to meet the demanding requirements of vascular stents. The use of two or more polymers (e.g., hybrid coatings) creates a drug delivery layer which permits the loading and elution control of a broad range of drugs or combinations of drugs from the surface of a stent. The inventive hybrid polymer binder controls the drug elution rate by using, e.g., various ratios of hydrophilic polymer to hydrophobic polymer, the combination stabilizing the drug during manufacturing, sterilization, and deployment of the stent.

Zhong does not teach a single outermost drug reservoir/release layer of two or more polymers, nor does it teach the controlled release system of the present invention. In fact, Zhong teaches that the second coating is covalently attached to the first/primer coating. For example, Zhong teaches that the cross-linking agents participate in covalently bonding the second coating composition containing a bio-active agent which has one or more organic acid functional groups to the polycarbonate-polyurethane composition through the excess organic acid functional groups on the polyfunctional cross-linking agent. Throughout Zhong, it is taught that the bio-active agents are covalently bound to the primer layer (e.g., column 5, lines 67-column 6, line 6, column 6, lines 62-

column 7, lines 6, column 9, lines 65-column 10, line 18, and column 10, lines 53-57). Functionally, Zhong's covalent bonding of drugs to the primer layer is quite different from the present invention, wherein the active agent is contained in and is later released from a single outermost drug reservoir layer comprising two or more polymers at an insertion site.

Claims 4, 15, 17, 20, 24-26, 29, 35-37, 49-52, and 58, depend from claim 1, and therefore include all of its elements. As discussed above for claim 1, Zhong does not teach, disclose or suggest a single outermost drug reservoir layer comprising two or more polymers. Therefore, Zhong does not anticipate any of these claims.

Applicants respectfully request that the rejection of claims 1, 4, 15, 17, 20, 24-26, 29, 35-37, 49-52, and 58 be withdrawn.

Claim Rejections - 35 U.S.C. §103

The Examiner has rejected claims 2, 5, 14, 23, 30, 47 and 59 under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,197,051 (Zhong) in view of U.S. Patent No. 5,380,299 (Fearnot). Applicants respectfully traverse.

Applicants contend that the Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143, because none of the cited references, whether alone or in combination, teach or expressly or impliedly suggest all of the limitations set forth in the present claims.

Claims 2, 5, 14, 23 and 30, depend from claim 1, and therefore include all of its elements. Independent claim 47 is a means-plus-function claim that requires a single outermost drug reservoir layer comprising two or more polymers, e.g., a stabilizing polymer and a toughening polymer. Independent claim 59 also requires a single outermost drug reservoir layer comprising two or more

polymers, e.g., at least one hydrophobic polymer and at least one hydrophilic polymer. As discussed above for claim 1, Zhong does not teach, disclose, or suggest a single outermost drug reservoir layer comprising two or more polymers. Therefore, Zhong does not render obvious any of these claims, alone or in combination.

Fearnot relates to an intravascular medical device having a structure shaped and sized for introduction into the vascular system of a patient including a base material and a coating of a thrombolytic agent on the base material. Fearnot does not cure the defects of Zhong because nowhere in Fearnot is a single outermost drug reservoir layer comprising two or more polymers taught, disclosed or suggested. Therefore, neither Zhong, nor Fearnot, whether applied alone or in combination, render the claims obvious.

Applicants respectfully request that the rejection of claims 2, 5, 14, 23, 30, 47 and 59 be withdrawn.

The Examiner has also rejected claims 16, 21, 22, 27, 38 and 53-57 under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,197,051 (Zhong) because allegedly the additional elements recited in these claims would be considered obvious by one skilled in the art. Applicants respectfully traverse.

Applicants contend that the Examiner has not established a *prima facie* case of obviousness because none of the cited references, whether alone or in combination, teach or expressly or impliedly suggest all of the limitations set forth in the present claims.

Claims 16, 21, 22, 27, 38 and 53-57, depend from claim 1, and therefore include all of its elements. As discussed above for claim 1, Zhong does not teach, disclose or suggest a single

outermost drug reservoir layer comprising two or more polymers. Therefore, Zhong does not anticipate, nor render obvious any of these claims.

Applicants respectfully request that the rejection of claims 16, 21, 22, 27, 38 and 53-57 be withdrawn.

The Examiner has rejected claims 3, 6-13, 18, 19, 28, 31-34 and 39-46 under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,197,051 (Zhong) in view of U.S. Patent No. 6,663,662 (Pacetti). Applicants respectfully traverse.

Applicants contend that the Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143, because none of the cited references, whether alone or in combination, teach or expressly or impliedly suggest all of the limitations set forth in the present claims.

Claims 3, 6-13, 18, 19, 28, 31-34 and 39-46, depend from claim 1, and therefore include all of its elements. As discussed above for claim 1, Zhong does not teach, disclose or suggest a single outermost drug reservoir layer comprising two or more polymers. Therefore, Zhong does not anticipate, nor render obvious any of these claims.

Moreover, Pacetti does not cure the defects of Zhong, because nowhere in Pacetti is a single outermost drug reservoir layer comprising two or more polymers taught, disclosed or suggested. As elaborated in previous responses to office actions in this case, which are hereby incorporated by reference, Pacetti teaches a device having a non-drug containing barrier in the outermost layer. Therefore, neither Zhong nor Pacetti, whether applied alone or in combination render the claims obvious.

Applicants respectfully request that the rejection of claims 3, 6-13, 18, 19, 28, 31-34 and 39-46 be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-47 and 49-59 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR §1.17, including extension of time fees pursuant to 37 CFR §1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

Respectfully submitted,

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